

REMARKSThe Claims

Claims 58-81 are cancelled without prejudice or disclaimer. Claims 82-92 have been added. The new claims are fully supported by the specification and do not introduce new matter and do not raise issues requiring further consideration and/or search. Entry of the new claims is requested.

Claims 64, 69, 75 and 81 are objected to under 37 CFR 1.75(c) as being improper multiple dependent claims. The claims have been cancelled rendering the rejection moot.

Rejections under 35 U.S.C. 112

Claims 69 and 81 are rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not contain a written description for "**a composition comprising an antibody** or fragment thereof **AND** BMP-1 to BMP12. transforming growth factor-b, a transforming growth factor- β family member ... " (Examiner's emphasis). The Examiner argues there is no support in the specification for the recited compositions. Applicants disagree.

Claims 69 and 81 have been cancelled and the subject matter thereof is recited in Claim 90.

To fulfill the written description requirement, a patent specification must describe an invention and do so in such a manner that one skilled in the art can clearly conclude that "the inventor invented the claimed invention" *University of California v. Eli Lilly and Co.* 43 USPQ2d 1404 (Fed. Cir. 1997) citing *Lockwood v. American Airlines Inc.* 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). There is no requirement that the claimed invention be literally present in the specification so long as it is clear that the applicant had possession of the invention as of the date of the application.

The Examiner alleges that support for claims 69 and 81 is found at p. 46, lines 7-9 and Example 11. Applicant points out that these sections of the specification were cited as support for recitation of an epitope comprising "at least part of the amino acid sequence ..." in present Claim 82. Support for Claim 90 is found at p. 23, lines 9-19 which discloses the administration of agonists or antagonists of OPGbp alone or in combination with bone morphogenic factors designated BMP-1 to BMP-12, transforming growth factor- β , and so forth. It is clear that in order to carry out such administration, one skilled in the art could use a composition of an OPGbp agonist and antagonist further comprising the other recited agents. Thus, Applicant had possession of the invention set forth in Claim 90 and thereby satisfied the written description requirement.

Claims 64 and 75 are rejected under 35 U.S.C. 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one to make and/or use the invention. It is argued that the specification does not teach how to make a transgenic animal and that undue experimentation would be required to make same.

In view of the Jakobovits (Curr. Opinion Biotech. 6, 561-566 (1995)) and Bruggerman et al. (Immunol. Today 17, 391-397 (1996)) references cited by the Examiner, teachings were available whereby one skilled in the art could construct a transgenic mouse capable of producing human antibodies. Those teachings could be used to make other transgenic animals capable of producing human antibodies. Citing the Jakobovits and Bruggerman references, the Examiner argues that making transgenic animals which are capable of producing heterologous antibodies is "extremely complex and unpredictable". Yet, there is no evidence that one could not use the teachings in the art to make a transgenic animal other than a transgenic mouse for producing human antibodies. Indeed, as explained in the Jakobovits and Bruggeman references, many crucial steps, such as the inactivation of the host Ig genes and expression of human Ig

genes upon transfer to the new host, have now been accomplished. Applicant maintains that the art enables the making of transgenic animals capable of producing human antibodies without undue experimentation.

Rejections under 35 U.S.C. 102

Claims 58, 60, 70 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al., U.S. Patent No. 6,419,929B1. Claims 59, 60, 71 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al., U.S. Patent No. 6,242,586.

Claims 58, 59, 60, 70, 71 and 72 are cancelled without prejudice or disclaimer, thereby rendering the rejection moot.

Rejection under 35 U.S.C. 103

Claims 62, 63, 65-68, 73, 74 and 77-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al., U.S. Patent No. 6,419,929B1 in view of Gorman et al., U.S. Patent No. 6,242,586B1. The Examiner argues that one skilled in the art would have been motivated to make the claimed antibodies in view of the disclosure of SEQ ID NO:39 in Anderson or the disclosure of SEQ ID NO:37 in Gorman.

Applicants have cancelled Claims 62, 63, 65-68, 73, 74 and 77-80 without prejudice or disclaimer, thereby rendering the rejection moot.

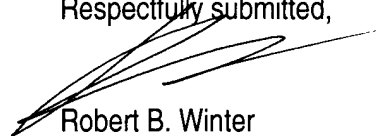
Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al., U.S. Patent No. 6,242,586B1 in view of Cabilly et al., U.S. Patent No. 4,816,567.

Applicant have cancelled Claim 76 without prejudice or disclaimer, thereby rendering the rejection moot.

CONCLUSION

Claims 82-92 are in condition for allowance and an early notice thereof is solicited.

Respectfully submitted,



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